

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
NORFOLK DIVISION**

CAREFIRST OF MARYLAND, INC.,  
GROUP HOSPITALIZATION AND  
MEDICAL SERVICES, INC., CAREFIRST  
BLUECHOICE, INC., and CFA, LLC d/b/a  
CAREFIRST ADMINISTRATORS, on  
behalf of themselves and all others similarly  
situated,

Plaintiffs,

v.

JOHNSON & JOHNSON and JANSSEN  
BIOTECH, INC.,

Defendants.

Case No. 2:23-cv-00629-JKW-LRL

ORAL ARGUMENT REQUESTED

**DEFENDANTS JOHNSON & JOHNSON AND JANSSEN BIOTECH, INC.'S  
SUPPLEMENTAL REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS**

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Pursuant to the Court’s June 17, 2024, July 9, 2024, and July 19, 2024 Orders, Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, “J&J” or “Defendants”) hereby submit this Supplemental Reply Brief in Support of their Motion to Dismiss.

### **INTRODUCTION**

Plaintiffs’ Response to J&J’s Supplemental Brief is an exercise in obfuscation. They apparently believe that if they throw up enough dust, they can obscure the fundamental deficiencies in their arguments. But instead, Plaintiffs’ need to rely—at every turn—on mischaracterizations of J&J’s arguments and on squarely inapposite case law only serves to highlight those deficiencies.

J&J’s Supplemental Brief cited on-point authority demonstrating that, as indirect purchasers, Plaintiffs lack standing to pursue their *Walker Process* claims under federal or state laws, particularly given that the alleged infringers—that is, the parties most directly impacted by the challenged conduct (a point that the Plaintiffs do not dispute)—chose to settle their disputes rather than pursue such claims and risk being enjoined for the life of the patents. J&J similarly cited on-point authority that Plaintiffs’ state law claims based on alleged fraud on the United States Patent and Trademark Office (“PTO”) are preempted. Despite the number of cases they cite, Plaintiffs do not, and cannot, point to any on-point authority to the contrary on either issue. Indeed, none of the cases they cite involves antitrust claims based solely on the acquisition of patents under federal patent law or implicates the type of standing concerns present in cases, like this one, involving such claims. As a result, Plaintiffs’ claims based on alleged fraud in the acquisition of the ’307 Patent should be dismissed on these grounds alone.

This result makes sense. Permitting indirect purchasers to maintain antitrust claims based on alleged *Walker Process* fraud, particularly when the alleged infringers—the parties against whom the ’307 Patent was enforced—have chosen to settle, would be inconsistent with the fundamental principles of both antitrust standing and preemption. And, in addition, permitting

indirect purchasers to second-guess the judgement of alleged infringers in entering into lawful and procompetitive settlement agreements, as Plaintiffs attempt to do here, would create perpetual uncertainty regarding the finality of all patent license and settlement agreements. Moreover, indirect purchasers do not face the risk of patent enforcement and allowing them to challenge a patent's enforceability without weighing the countervailing risk of being excluded from the market during the patent term would increase the cost of enforcement and undermine the value of patents.

In sum, as indirect purchasers, Plaintiffs are simply not proper parties to pursue claims based on alleged fraud in the acquisition of the '307 Patent and, even if they were, their claims are preempted by federal law. Nothing in Plaintiffs' Response suggests otherwise.

### **ARGUMENT**

#### **I. *Illinois Brick* (and *Illinois Brick* Repealer Laws) Are Irrelevant to the AGC Analysis.**

Plaintiffs spend most of their brief trying to blur the distinction between two fundamentally different and independent questions: (1) whether indirect purchasers are permitted to seek damages under federal antitrust law (not at issue here) and, separately, (2) whether, as a general matter, a plaintiff has antitrust standing to bring an antitrust claim (the issue in this case). But, as Plaintiffs concede, those questions are separate and independent. *See* Pls.' Supp. Br., Dkt. 98 at 5 (noting that the issues are "analytically distinct"). The first question regarding the availability of damages is governed by *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) for federal claims and the existence (or not) of *Illinois Brick* repealer laws for state law claims. The second question regarding antitrust standing (regardless of remedy) is governed by AGC, where the Supreme Court has laid out a five-factor framework to assess whether *any* plaintiff—not just an indirect purchaser—is an efficient enforcer of the antitrust laws and "a proper party to bring a private antitrust action." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*,

459 U.S. 519 at 535 n.31 (1983) (hereinafter, “AGC”).<sup>1</sup> And *only* the question of whether Plaintiffs have antitrust standing—as governed by AGC and its progeny—is relevant to the analysis here.<sup>2</sup>

Nonetheless, Plaintiffs argue that the mere existence of *Illinois Brick* repealer laws in some states somehow avoids the need to engage in antitrust standing analysis or lessens a plaintiff’s burden under AGC in those states. *See* Pls.’ Supp. Br., Dkt. 98 at 8, 13, 15. This is wrong. As numerous decisions make clear, even in situations where states have passed *Illinois Brick* repealer laws and permit indirect purchasers to seek damages, those indirect purchasers—like all other antitrust plaintiffs—must independently establish antitrust standing to bring their claims. And courts typically determine standing by applying the AGC factors, not by, as Plaintiffs claim, “treat[ing] end payor standing under state antitrust law as a non-issue.” *Id.* at 8. In other words, the fact that indirect purchasers are permitted to seek damages under state law if they have standing to bring an antitrust claim cannot answer the question of whether they have the requisite standing to do so.

The decision in *Kanne v. Visa U.S.A. Inc.*, 723 N.W.2d 293 (Neb. 2006) is instructive. There, the Nebraska Supreme Court explained that although the Nebraska Legislature passed an *Illinois Brick* repealer law, that law “simply removed the automatic bar against indirect purchaser actions announced in *Illinois Brick*” and “did not eliminate [the] separate and distinct antitrust standing requirements that bar [plaintiffs’] claims.” *Id.* at 300. The court had no problem applying AGC and dismissing plaintiffs’ “remote” claims, particularly when, like here, “more directly

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<sup>1</sup> That same test, or one based on similar principles, applies to state law claims as well.

<sup>2</sup> Courts frequently grant motions to dismiss for lack of antitrust standing because it is a threshold legal issue. *See, e.g., Glob. Tel\*Link Corp. v. JACS Sols. Inc.*, No. 1:23-CV-179, 2023 WL 8918281, at \*12 (E.D. Va. Dec. 27, 2023) (granting motion to dismiss on antitrust standing grounds); *DataCell ehf. v. Visa, Inc.*, No. 1:14-CV-1658 GBL/TCB, 2015 WL 4624714, at \*11 (E.D. Va. July 30, 2015) (same).



injured parties” chose to settle. *See id.* at 297-98. Similarly, even though Connecticut has an *Illinois Brick* repealer law, *see* Conn. Gen. Stat. Ann. § 35-46a, its Supreme Court has held that “a plaintiff must adequately plead both that it has suffered an antitrust injury and that it is an efficient enforcer of the antitrust act” in order “to have standing to bring a claim” under Connecticut antitrust law. *Tremont Pub. Advisors, LLC v. Connecticut Res. Recovery Auth.*, 217 A.3d 953, 966 (Conn. 2019). The list goes on.<sup>3</sup>

In short, Plaintiffs are attempting to rely on *Illinois Brick* repealer laws as a shortcut around the AGC analysis. But the law supports no such shortcut.

## **II. Plaintiffs Fail to Meet the AGC Factors to Establish Antitrust Standing.**

Plaintiffs rely on fundamentally misplaced authority in claiming that they satisfy the AGC factors here. In support of their argument that indirect purchasers have standing under AGC, including for their state law claims,<sup>4</sup> Plaintiffs primarily rely on a trio of cases—*Suboxone*, *Propranolol*, and *Lorazepam*. *See* Pls.’ Supp. Br., Dkt. 98 at 8-10 (citing *In re Suboxone*

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<sup>3</sup> *See, e.g., Southard v. Visa U.S.A. Inc.*, 734 N.W.2d 192, 198-99 (Iowa 2007) (applying AGC factors despite *Illinois Brick* repealer law); *Nev. Recycling & Salvage, Ltd. v. Reno Disposal Co., Inc.*, 423 P.3d 605, 607-08 (Nev. 2018) (same); *see also* Defs.’ Supp. Br., Dkt. 92 at 10-11 & exs. A & B (collecting cases in Arizona, California, District of Columbia, Kansas, Maine, Michigan, New Mexico, New York, North Carolina, North Dakota, South Dakota, Vermont, and Wisconsin where state courts have applied AGC despite *Illinois Brick* repealer laws). Even one of the cases Plaintiffs highlight recognizes that *Illinois Brick* repealer laws do not obviate the need for an antitrust standing analysis under AGC. *See In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig.*, No. 9-cv-3690, 2015 WL 3988488, at \*6 (N.D. Ill. June 29, 2015) (“[T]he Court notes that while at least 25 states enacted repealer statutes in response to *Illinois Brick* . . . the Court is not aware of any legislative action by any state expressly rejecting AGC. The fact that so many states took action in response to *Illinois Brick* shows that states are quite capable of rejecting federal antitrust law when they see fit to do so.”).

<sup>4</sup> For Plaintiffs’ state law antitrust claims, Plaintiffs admit that most of the states would apply AGC or a modified version of AGC, *see* Appendix A to Pls.’ Supp. Br., Dkt. 98-1, and that their state law antitrust claims would rise and fall along with their federal law claims, *see* Pls.’ Supp. Br., Dkt. 98 at 15 (“[B]ecause the end payors meet the AGC test for standing, this Court need not analyze which states have adopted AGC interpreted in light of the *Illinois Brick* repealers.”).

(*Buprenorphine Hydrochloride & Naloxone*) *Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014); *In re Propranolol Antitrust Litig.*, 249 F. Supp. 3d 712 (S.D.N.Y. 2017); *In re Lorazepam & Clorazepate Antitrust Litig.*, 295 F. Supp. 2d 30 (D.D.C. 2003)). None is controlling and none is on point because, importantly, none involves claims of *Walker Process* fraud, patent enforcement, or instances where the party directly affected by the acquisition and enforcement of a patent has chosen to settle rather than risk being enjoined.<sup>5</sup> Therefore, none involves issues arising from the indirect purchasers' attenuated relationship to patent acquisition, the considerations principally driving the antitrust standing analysis in a *Walker Process* and patent acquisition case like this one.

Instead, the antitrust claims in Plaintiffs' cases involved commercial conduct in the marketplace, to which end purchasers had a far more proximate and direct relationship. For example, *Propranolol* involved an alleged *per se* unlawful price-fixing conspiracy among competitors to raise the price of a generic drug, propranolol, to combat the drug's steadily declining price. *Propranolol*, 249 F. Supp. 3d at 718-724. Similarly, in *Lorazepam*, the defendant allegedly entered into exclusive licensing agreements with all of the suppliers of a necessary ingredient, and then charged supracompetitive prices to consumers. *Lorazepam*, 295 F. Supp. 2d at 33. *Suboxone* involved a defendant's alleged "product hopping" of an opioid dependence drug from tablet to film form to unlawfully maintain its monopoly power, as well as allegations of "a fraudulent sales and marketing campaign" which directly reached end payors. *Suboxone*, 64 F. Supp. 3d at 674, 680. Unlike the case at bar, the alleged unlawful conduct was targeted directly at the class

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<sup>5</sup> Plaintiffs chide Defendants for the number of cases they cite, but it is quality not quantity that matters. Defendants' cited cases on this issue are directly on point and concern standing for indirect purchasers alleging antitrust claims based on *Walker Process* fraud. *See* Defs.' Supp. Br., Dkt. 92 at 6-7 (citing *Farag v. Health Care Serv. Corp.*, No. 17 C 2547, 2017 WL 2868999 (N.D. Ill. July 5, 2017); *In re K-Dur Antitrust Litig.*, No. CIV.A. 01-1652 (JAG), 2007 WL 5297755 (D.N.J. Mar. 1, 2007)).

representatives.

Plaintiffs further argue that under *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302 (4th Cir. 2007), “since the non-competitor, non-purchaser claim in *Novell* satisfied the Fourth Circuit’s application of *AGC* that reasoning would lead to the same result for an end payor drug purchaser.” Pls.’ Supp. Br., Dkt. 98 at 10, n.43. But *Novell* actually leads to the opposite conclusion. In that case, plaintiff Novell marketed a competing suite of office productivity products to Microsoft Office and alleged that Microsoft’s conduct “had the effect of thwarting the ability of Novell’s products to lower the applications barrier to entry into the operating-system market, therefore harming competition in that market.” 505 F.3d at 316. While Novell did not compete in the operating system market, the unique nature of the software industry meant that the harm visited by Microsoft on Novell’s office productivity suite allowed Microsoft to retain its operating system monopoly. *Id.* at 309. Therefore, Novell was far more proximate to the alleged wrongdoing than the indirect purchaser Plaintiffs in this case. In addition, in *Novell*, the Fourth Circuit found that Novell was likely the only entity that could have brought suit. *Id.* at 318-319. Here, by contrast, highly sophisticated parties could have brought suit and either engaged in a lawsuit (Amgen) or were prepared to do so (the other manufacturers), but in each instance they chose to resolve their disputes by entering into pro-competitive settlements. In short, highly sophisticated competitor manufacturers were well-positioned to evaluate challenges based on J&J’s patent acquisitions but chose settlements instead.

Therefore, none of Plaintiffs’ cases extend antitrust standing doctrine to permit indirect purchasers to pursue the *Walker Process* fraud claim Plaintiffs want to bring here.<sup>6</sup> In this case,

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<sup>6</sup> None of the other cases Plaintiffs cite helps them either. Like *Propranolol* and *Lorazepam*, *In re Interior Molded Doors Antitrust Litig.*, No. 3:18-CV-00718-JAG, 2019 WL 4478734, at \*1

the alleged anticompetitive conduct for purposes of antitrust standing concerns J&J's alleged fraudulent conduct before the PTO in the acquisition of the '307 Patent.<sup>7</sup> Courts analyzing such claims have concluded that the relationship of indirect purchasers to this type of patent conduct is too attenuated to confer standing. *See* Defs.' Supp. Br., Dkt. 92 at 2-8.<sup>8</sup> And the parties that have the most direct relationship to this alleged misconduct—*i.e.*, the biosimilar manufacturers—chose to settle their claims for early entry dates rather than pursue them and risk being enjoined from entering for the life of J&J's patents.

This distinction matters. As discussed above, the attenuated relationship of indirect purchasers to the alleged patent conduct implicates very different considerations than those at issue

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(E.D. Va. Sept. 18, 2019) is inapposite because it is a *per se* unlawful price-fixing case involving commercial conduct in the marketplace. The claims in *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395 (3d Cir. 2000) are also distinguishable because, like the claims in *Suboxone*, they were based on allegations that the defendant “disseminat[ed] . . . false and misleading information to the public regarding generic warfarin sodium.” *Warfarin*, 214 F.3d at 397. Unlike the patents in this case, which were only asserted against other manufacturers, the allegedly unlawful behavior in *Warfarin* was targeted directly at the plaintiffs. And, as J&J has already explained, *In re DDAVP* involved a “tarnished” patent that had already been found to be unenforceable due to inequitable conduct. *See* Defs.' Reply Br. ISO MTD, Dkt. 65 at 15-16. It does not implicate the same antitrust standing concerns as Plaintiffs' claims here, where remote indirect purchasers want to litigate the validity of the '307 Patent anew and second-guess the judgment of litigants who chose to enter into procompetitive settlements with J&J. The other cases Plaintiffs cite in their Appendix B are similarly distinguishable, as explained in Exhibit B.

<sup>7</sup> In their earlier briefing, Plaintiffs made clear that their claims are not based on allegations that J&J's settlements were themselves unlawful (under *Actavis* or otherwise) or that J&J engaged in bad faith, sham litigation. *See, e.g.*, Pls.' Opp. Br., Dkt. 57, at 29 (“[P]urchasers do not allege the *settlements* violate the Sherman Act.”). The alleged fraud on the PTO is the only alleged anticompetitive conduct related to the '307 Patent.

<sup>8</sup> Plaintiffs incorrectly interpret Defendants' argument to be that damages are speculative and cannot be apportioned. *See* Pls.' Supp. Br., Dkt. 98 at 11 (claiming that “as to whether damages are speculative and can be apportioned, *Propranolol*, *Suboxone*, and *Lorazepam* all conclude that health benefit provider damages are not speculative.”). This is not Defendants' argument. Instead, Defendants' argument is based on the attenuated relationship between the indirect purchasers and the Defendants' patent.

in the cases that Plaintiffs cite, particularly where, as here, the alleged infringers, the biosimilar manufacturers, have chosen to settle. The biosimilar manufacturers against whom the '307 Patent was enforced were the parties most directly impacted by the alleged conduct here. And, in addition, they had every incentive to pursue challenges to the '307 Patent rather than settle if doing so would allow them to enter the marketplace sooner. The Plaintiffs have alleged no facts to the contrary. Nor do the Plaintiffs suggest there was anything wrongful about the settlement agreements themselves. *See, e.g.,* Pls.' Opp. Br., Dkt. 57, at 29 (“[P]urchasers do not allege the *settlements* violate the Sherman Act. As result, . . . *Actavis*[] and other reverse payment case law is irrelevant.”).

If indirect purchasers are permitted to second-guess the judgement of alleged infringers in entering into lawful and procompetitive settlement agreements, as Plaintiffs attempt to do here, it would allow them to undo virtually any patent settlement agreement and re-litigate issues that the parties to the actual litigation chose to resolve. And they would be able to do so free of the countervailing risk of being enjoined under the patent because they are not subject to suits for infringement. That is fundamentally at odds with the way the patent system is supposed to operate and would undermine the value of patents and the finality of settlement agreements.

Separately, Plaintiffs attempt to draw the misplaced distinction that a claim for injunctive relief under Section 16 of the Clayton Act, as opposed to monetary damages, does not require application of the AGC factors. Not so. Courts apply AGC to claims for injunctive relief under Section 16, as well as claims for damages. *See e.g., In re K-Dur Antitrust Litig.*, Case No. 2:01-cv-01652-SRC-CLW, Dkt. No. 98 at ¶ 97 (D.N.J. Mar. 4, 2002) (Consolidated Class Action Complaint) (alleging that “Plaintiffs and the Class seek the issuance of an injunction prohibiting Defendants’ continued compliance with the terms of the unlawful Agreements” under Section 16

of the Clayton Act) (attached as Ex. A); *Pocahontas Supreme Coal Co. v. Bethlehem Steel Corp.*, 828 F.2d 211, 220 (4th Cir. 1987) (“[J]ust as the causal connection between harm and violation was too attenuated to support standing to seek such a treble damages remedy, it is too attenuated to permit prosecution of a claim for injunctive relief.”). Indeed, if it were otherwise, *AGC* would never apply to federal antitrust claims by indirect purchasers because they can *only* bring such claims for injunctive relief.

Finally, Plaintiffs mistakenly claim that Defendants did not address standing for their remaining consumer protection and unjust enrichment claims under state law. Defendants did address these claims, citing to proximate cause principles akin to the *AGC* factors to demonstrate why Plaintiffs lack standing to bring them. *See* Defs.’ Supp. Br., Dkt. 92 at 15-16. Plaintiffs have not substantively responded to these arguments.

### **III. Plaintiffs’ State Law Claims Are Preempted by Federal Law.**

#### **A. The Sole Basis of Plaintiffs’ Claims Is Alleged Fraud on the PTO, Necessitating a Finding of Preemption.**

Contrary to Plaintiffs’ arguments, state law claims based solely on allegations of fraud on the PTO are preempted by federal patent law. And Plaintiffs’ theories of anticompetitive conduct involve nothing more than alleged misconduct in prosecuting the ’307 Patent. As noted above, Plaintiffs’ Opposition to the Motion to Dismiss expressly acknowledges that the settlements between J&J and biosimilars manufacturers were *not* anticompetitive. *See, e.g.*, Pls.’ Opp. Br., Dkt. 57, at 29. Conduct before the PTO is inherently the subject of federal patent law and cannot be subject to state law.

Plaintiffs’ cases on this issue are readily distinguishable. In none was the alleged wrongdoing exclusively limited to the manner in which a defendant prosecuted a patent before the PTO under federal patent law. Pls.’ Supp. Br., Dkt. 98 at 17-18. Rather, each also involved what

the courts characterized as wrongdoing “in the marketplace”—namely, allegedly paying potential competitors to stay out of the market in “reverse payment” settlements. Plaintiffs have admitted such conduct is not at play here and, therefore, preemption applies.

For example, in *Loestrin*, which Plaintiffs feature in their brief, the court explained that “[c]ourts have held that when the state law cause of action provides a remedy for conduct that occurs *entirely before the PTO*—such as inequitable conduct before the PTO—or for ‘patent-like protection,’ it is preempted by federal patent law.” *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 356 (D.R.I. 2017) (citing *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1380-83 (Fed. Cir. 2000)) (emphasis added).<sup>9</sup> *Loestrin* did not involve alleged conduct entirely before the PTO. Instead, it involved claims directed to (1) a patent that was procured by fraud on the PTO and thereafter enforced in the marketplace in bad faith, and (2) a reverse payment settlement. *Id.* at 355-358. In rejecting the defendants’ preemption argument, the court emphasized that, in so-called “reverse payment” cases, “the Supreme Court has acknowledged that ‘[i]t is normally not necessary to litigate patent validity to answer the antitrust question’ as ‘[a] large, unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the patent’s validity.’” *Id.* at 357.

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<sup>9</sup> Plaintiffs suggest that there are differences in analyzing *Walker Process* fraud and inequitable conduct. *See, e.g.*, Pls.’ Supp. Br., Dkt. 98 at 17 n.79 (“[A] state law claim would lie because it would address a different wrong than a claim for inequitable conduct before the PTO.”). But that is not the law following the Federal Circuit’s decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), which heightened the inequitable conduct standard. *See, e.g.*, *TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016) (“After *Therasense*, the showing required for proving inequitable conduct and the showing required for proving the fraud component of *Walker Process* liability may be nearly identical.”).



Likewise, both *Effexor* and *Lipitor* involved allegedly unlawful settlements and explained that “even if a state court must adjudicate a question of federal patent law, it is not preempted *if it includes additional elements not part of a federal cause of action.*” *In re Effexor Antitrust Litig.*, 337 F. Supp. 3d 435, 450 (D.N.J. 2018) (emphasis added); *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 410 (D.N.J. 2018) (“[B]ecause Plaintiffs’ antitrust claims do not implicate federal patent law, the Court will not dismiss these claims based on preemption.”).<sup>10</sup>

Additionally, Plaintiffs’ citation to *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998), is inapposite. *Hunter Douglas* was decided before *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001) and its progeny, and it did not actually reach a decision on preemption; instead, the court remanded for further consideration in light of its general guidance. 153 F.3d at 1337. Further, *Hunter Douglas* involved a patent holder sending threats to customers of its competitors. *Id.* at 1322. Unlike here, the conduct at issue went well beyond simply maintaining and asserting a patent. The Federal Circuit has since explained that when the state law cause of action provides a remedy for conduct that occurs entirely before the PTO, it is preempted by federal patent law. *Semiconductor Energy Lab. Co.*, 204 F.3d at 1380-83.

In this case, Plaintiffs’ allegations do not contain additional elements not part of a federal cause of action. Rather, Plaintiffs’ allegations related to the ’307 Patent are exclusively directed to obtaining that patent through alleged “misrepresentations” and “omissions” to the PTO by J&J’s

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<sup>10</sup> Plaintiffs’ other cases similarly involve misconduct in the marketplace, specifically unlawful settlements. *In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1333-34 (D. Kan. 2018) (alleging anticompetitive practices including patent misuse, reverse “pay-for-delay” settlements, and sham citizens’ petitions); *Picone v. Shire PLC*, No. 16-CV-12396-ADB, 2017 WL 4873506, at \*14 (D. Mass. Oct. 20, 2017) (“Here, the remaining claims are based on tortious conduct in the marketplace—*i.e.*, the purportedly illegal settlement agreements—that require different elements than any arguably corresponding federal patent law claim (such as patent invalidity), and are therefore not protected or governed by federal patent law”); *see also* Ex. B.



patent counsel. *See* Am. Compl. ¶¶ 338-393. Consequently, if Plaintiffs’ state law claims were permitted to proceed, this Court will be required to apply state law claims to evaluate J&J’s alleged conduct before the PTO and the resulting validity and enforceability of the ’307 Patent. Those are exactly the types of questions that must be decided by applying federal law, and only federal law.

**B. *Buckman* Preemption Applies to Conduct Before the PTO and Other Federal Agencies.**

Plaintiffs improperly attempt to cabin the Supreme Court’s guidance in *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001). They argue “J&J misreads the Supreme Court’s *Buckman* decision as supporting the expansive proposition that federal law *generally* preempts *any* claim of fraud on a federal agency.” Pls.’ Supp. Br., Dkt. 98 at 19-20. Not so. The guidance of *Buckman* is clear that state law claims based on fraud on a federal agency—any federal agency—are preempted by federal law.

*Buckman* is not limited to a “highly complex federal regime for regulating medical devices.” *Id.* at 19. The reasoning in *Buckman* was straightforward—the federal scheme empowered the FDA to punish and deter fraud, and the agency used that authority to balance several statutory objectives, which state-law fraud-on-the-agency claims would skew. *Buckman*, 531 U.S. at 348. The Supreme Court in *Buckman* reasoned generally that “the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.” *Id.* at 347 (internal quotations omitted).

Consequently, federal preemption as set forth in *Buckman* has been repeatedly applied in the context of multiple federal acts, regulatory schemes, and agencies outside the context of misconduct before the FDA. *See, e.g., In re Ford Motor Co. F-150 & Ranger Truck Fuel Econ. Mktg. & Sales Pracs. Litig.*, 65 F.4th 851, 861-62, 865-67 (6th Cir. 2023), *cert. denied sub nom.*

*LLoyd v. Ford Motor Co.*, 144 S. Ct. 332 (2023) (affirming district court’s dismissal of complaint on the grounds that federal law governing the Environmental Protection Agency both expressly and impliedly preempted plaintiffs’ claims, emphasizing that “*Buckman* and its progeny apply with equal force” to “the regulatory scheme governing the EPA’s approval of fuel economy estimates”); *Geo Grp., Inc. v. Newsom*, 50 F.4th 745, 761-63 (9th Cir. 2022) (applying *Buckman* and holding that a California state statute is likely preempted by the power Congress has conferred to Immigration and Customs Enforcement to carry out extensive detention operations); *In re Vehicle Carrier Servs. Antitrust Litig.*, 846 F.3d 71, 86-87 (3d Cir. 2017), *as amended* (Jan. 25, 2017) (citing *Buckman* and affirming district court’s dismissal of complaint because “the [federal] Shipping Act preempts IPPs’ state law consumer protection and unjust enrichment claims because allowing them to proceed would pose an obstacle to achieving Congress’s objectives in passing the Act”); *US Airways, Inc. v. O’Donnell*, 627 F.3d 1318, 1321-22, 1325 (10th Cir. 2010) (applying *Buckman* and holding that the Federal Aviation Act excludes state regulation and a New Mexico regulatory scheme “is impliedly preempted as it falls within the field of aviation safety that Congress intended federal law to occupy exclusively”); *Farina v. Nokia Inc.*, 625 F.3d 97, 122-24, 133-34 (3d Cir. 2010) (applying *Buckman* and affirming district court’s dismissal of complaint on the ground that plaintiff’s claims are preempted by regulations promulgated by the Federal Communications Commission); *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204-07 (9th Cir. 2002) (affirming district court’s dismissal of complaint on the grounds that federal law governing the Environmental Protection Agency both expressly and impliedly preempted plaintiffs’ claims).

Plaintiffs argue *LCS* and *Lockwood* are not instructive because “[t]hose cases dealt with: (1) the fraudulent filing of an *inter partes* review petition; and (2) the fraudulent initiation of patent

reexamination proceedings (i.e., actions to *invalidate* patents, not obtain them).” Pls.’ Supp. Br., Dkt. 98 at 20 n.93. These distinctions are irrelevant. Both *LCS* and *Lockwood* dismiss state law claims where—*exactly* like Plaintiffs’ allegations here—the allegations amounted to “no more than [claims alleging] bad faith misconduct before the PTO.” *Lockwood v. Sheppard, Mullin, Richter & Hampton, LLP*, 2009 WL 9419499, at \*7 (C.D. Cal. Nov. 24, 2009) (citing *Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1477 (Fed. Cir. 1998)). *LCS*, addressing *Buckman* and following *Lockwood*, illustrates why Plaintiffs’ attempt to cabin *Buckman* should be rejected:

In *Lockwood v. Sheppard, Mullin, Richter & Hampton, LLP*, an analogous case, the court held that fraud claims based upon an allegedly fraudulent reexamination request filed with the PTO were preempted by federal patent law under *Buckman*. The *Lockwood* Court held that such claims are “no more than claims alleging bad faith misconduct before the PTO.” *The Court finds, therefore, that to allow LCS to bring fraud claims based on alleged misconduct before the PTO “would be ‘contrary to Congress’ preemptive regulation in the area of patent law.”* *LCS’s* fraud claims based on the IPR petition are, therefore, preempted by federal patent law.

*LCS Group, LLC v. Shire LLC*, 2019 WL 1234848, at \*6 (S.D.N.Y. Mar. 8, 2019) (internal citations omitted) (emphasis added).

### **C. J&J Cannot Waive its Preemption Argument.**

Lastly, Plaintiffs suggest that Defendants have waived any preemption argument, and “J&J’s entire preemption argument should be struck.” Pls.’ Supp. Br., Dkt. 98 at 20. However, the Supreme Court has recognized that the defense of preemption is jurisdictional, and therefore non-waivable. *See Int’l Longshoremen’s Assoc. v. Davis*, 476 U.S. 380, 390-91 (1986); *Olympic Pipe Line Co. v. City of Seattle*, 437 F.3d 872, 883 (9th Cir. 2006) (“Preemption is a power of the federal government, not an individual right of a third party that the party can ‘waive.’”).

### **CONCLUSION**

For the foregoing reasons, J&J respectfully requests that the Court dismiss Plaintiffs’ Amended Complaint with prejudice.

Dated: July 22, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 22, 2024, I caused to be served a copy of the foregoing Memorandum in Support of Defendants' Supplemental Reply Brief in Support of Motion to Dismiss on all counsel of record via the Court's CM/ECF system.

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